

TRANSMITTAL FORM

Application Number: 10/072,320
 Filing Date: February 7, 2002
 First Named Inventor: Russell Mumper
 Art Unit: 1615
 Examiner Name: Berko, Retford O.
 Attorney Docket Number: NANO-002USD1

Total Number of Pages in this Submission: _____

ENCLOSURES (check all that apply)

- | | | |
|---|--|---|
| <input type="checkbox"/> Fee Transmittal Form
<input type="checkbox"/> Fee Attached
<input type="checkbox"/> Amendment/Reply
<input type="checkbox"/> After Final
<input type="checkbox"/> Affidavits/declaration(s)
<input type="checkbox"/> Extension of Time Request
<input type="checkbox"/> Express Abandonment Request
<input checked="" type="checkbox"/> Information Disclosure Statement
<input checked="" type="checkbox"/> Form PTO-1449
<input checked="" type="checkbox"/> References <u>A3-7, C1-43</u>
<input type="checkbox"/> Certified Copy of Priority Documents
<input type="checkbox"/> Reply to Missing Parts/
Incomplete Application
<input type="checkbox"/> Reply to Missing
Parts/Requirements
<input type="checkbox"/> Declaration(s) _____
<input type="checkbox"/> Copy of Notice of Missing
Parts/Requirements | <input type="checkbox"/> Drawings(s) _____
<input type="checkbox"/> Licensing-related Papers
<input type="checkbox"/> Petition
<input type="checkbox"/> Petition to Convert to a Provisional
Application
<input type="checkbox"/> Power of Attorney, Revocation,
Change of Correspondence
Address
<input type="checkbox"/> Statement under 37 CFR §3.73(b)
<input type="checkbox"/> Designation of Patent Practitioners
<input type="checkbox"/> Terminal Disclaimer
<input type="checkbox"/> Request for Refund
<input type="checkbox"/> CD, Number CD(s) _____
<input type="checkbox"/> Landscape Table on CD | <input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Appeal Communication to Board of
Appeals and Interferences
<input type="checkbox"/> Appeal Communication to TC
(Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Status Letter
<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below)
<input checked="" type="checkbox"/> Check in the amount of \$180.00
<input checked="" type="checkbox"/> Authorized to be charged to deposit account
if check insufficient or inadvertently omitted
Deposit account number: <u>50-</u>
<u>1212/NANO-002USD1</u>
<input type="checkbox"/> Sequence Statement
<input type="checkbox"/> Paper Copy of Sequence Listing
<input type="checkbox"/> Computer Readable Form (CRF)
<input checked="" type="checkbox"/> Postcard
<input type="checkbox"/> _____
<input type="checkbox"/> _____ |
|---|--|---|

Remarks:

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Fulbright & Jaworski, L.L.P.	Customer Number	32425
Signature	<i>Michael C. Barrett</i>		
Printed Name	Michael C. Barrett	Reg. No.	44,523
Date	October 6, 2005		

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: MS AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	<i>Michael C. Barrett</i>		
Typed or Printed Name	Michael C. Barrett	Date	October 6, 2005



PATENT

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Russell Mumper and Michael Jay

Serial No.: 10/072,320

Filed: February 4, 2002

For: pH-SENSITIVE MUCOADHESIVE FILM-
FORMING GELS AND WAX-FILM
COMPOSITES SUITABLE FOR
TOPICAL AND MUCOSAL DELIVERY
OF MOLECULES

Group Art Unit: 1615

Examiner: Berko, Retford O.

Atty. Dkt. No.: NANO:002USD1

10/12/2005 HLE333 00000007 10072320

01 FC:1806 180.00 OP

CERTIFICATE OF MAILING
37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: MS AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below:

October 6, 2005

Date

Michael C. Barrett

Michael C. Barrett

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

MS AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R. §§ 1.97(g), (h), this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be

25577889.1

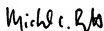
construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

This application is a divisional application of Serial No. 09/748,133, filed December 27, 2000 and is relied upon for an earlier filing date under 35 U.S.C. § 120. In accordance with Rule 37 C.F.R. § 1.98(d) copies of the listed documents are not enclosed as they have been previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. 09/748,133.

A fee as set forth in 37 C.F.R. § 1.17(p) in the amount of \$180.00 is enclosed. If an appropriate check has not been enclosed, or if it is insufficient, the Commissioner is authorized to deduct the appropriate fee from Fulbright & Jaworski Account No.: 50-1212/NANO:002USD1.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



Michael C. Barrett
Reg. No. 44,523
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 474-5201

Date: October 6, 2005

Form PTO-1449 (modified)

Atty. Docket No.
NANO:002USD1Serial No.
10/072,320

List of Patents and Publications for Applicant's

Applicant
Russell Mumper and Michael Jay

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Filing Date:
February 7, 2002Group:
1615U.S. Patent Documents
See Page 1Foreign Patent Documents
See Page 1Other Art
See Page 1

U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A3	3,922,260	11/25/75	Peniston et al.	260	211	08/24/73
	A4	5,102,666	04-1992	Acharya	424	487	
	A5	5,362,737	11/1994	Vora et al.	514	291	
	A6	5,446,070 A	08-1995	Mantelle, Juan A.	514	772.6	
	A7	5,639,469	06-1997	Benes et al.	424	435	

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	Bechgaard et al., "Solubilization of various benzodiazepines for intranasal administration, a pilot study," <i>Pharm Dev Tech</i> , 2:293-296, 1997.
	C2	Binnie et al., "Aflexanox oral paste: a novel treatment that accelerates the healing of aphthous ulcers," <i>Compend Contin Educ Dent</i> , 18:1116-1118, 1997.
	C3	Casetta and Negretti, "Salivary immune responses after gingival immunization with tetravaccinal and bivalent formulations of inactivated micro-organisms," <i>Dev Biol Stand</i> , 92:317-321, 1998.
	C4	Chang, "Stability of hirudin, a thrombin-specific inhibitor," <i>J Biol Chem</i> , 266:10839-10843, 1991.
	C5	Epic and Caroline, "Influence of storage conditions on the activity of recombinant hirudin," <i>Thromb Res</i> , 61:87-89, 1991.
	C6	Eriksson et al., "Prevention of thromboembolism with use of recombinant hirudin. Results of a double-blind, multicenter trial comparing the efficacy of desirudin (Revasc) with that of unfractionated heparin in patients having a total hip replacement," <i>J Bone Joint Surg Am</i> , 79:326-333, 1997.

25577817.1

EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)

Atty. Docket No.

NANO:002USD1

Serial No.

10/072,320

List of Patents and Publications for Applicant's

Applicant

Russell Mumper and Michael Jay

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Filing Date:

February 7, 2002

Group:

1615

U.S. Patent Documents

See Page 1

Foreign Patent Documents

See Page 1

Other Art

See Page 1

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C7	Esslinger <i>et al.</i> , "Pharmacodynamic and safety results of PEG-hirudin in healthy volunteers," <i>Throm Haemost</i> , 77:911-919, 1997.
	C8	Etchart <i>et al.</i> , "Class I-restricted CTL induction by mucosal immunization with naked DNA encoding measles virus hemagglutinin," <i>J Gen Virol</i> , 78:1577-1580, 1997.
	C9	Fenton <i>et al.</i> , "Thrombin inhibition by hirudin: how hirudin inhibits thrombin," <i>Haemostasis</i> , 21:27-31, 1991.
	C10	Fenton, "Thrombin interactions with hirudin," <i>Semin Thromb Hemost</i> , 15:265-268, 1989.
	C11	Garcia-Closas <i>et al.</i> , "Epidemiologic determinants of vaginal pH," <i>Am J Obstet Gynecol</i> , 180:1060-1066, 1999.
	C12	Heath <i>et al.</i> , "Mechanism of triclosan inhibition of bacterial fatty acid synthesis," <i>J Biol Chem</i> , 274:11110-11114, 1999.
	C13	Hjortkjaer <i>et al.</i> , "Single- and repeated-dose local toxicity in the nasal cavity of rabbits after intranasal administration of different glycols for formulations containing benzodiazepines," <i>J Pharm Pharmacol</i> , 51:377-386, 1999.
	C14	Jones <i>et al.</i> , "Targeting and delivery of bactericide to adsorbed oral bacteria by use of proteoliposomes," <i>Biochim Biophys Acta</i> , 1147:251-261, 1993.
	C15	Khandwala <i>et al.</i> , "5% amlexanox oral paste, a new treatment for recurrent minor aphthous ulcers: I. clinical demonstration of acceleration of healing and resolution of pain," <i>Oral Surg Oral Med Oral Pathol Oral Radiol Endod</i> , 83:222-230, 1997a.
	C16	Khandwala <i>et al.</i> , "5% amlexanox oral paste, a new treatment for recurrent minor aphthous ulcers: II. Pharmacokinetics and demonstration of clinical safety," <i>Oral Surg Oral Med Oral Pathol Oral Radiol Endod</i> , 83:231-238, 1997b.
	C17	Leung and Eikeler, "Eudragit E as a coating material for the pH-controlled drug release in the topical treatment of inflammatory bowel disease (IBD)," <i>J Drug Targeting</i> , 6:85-94, 1998.
	C18	Leung <i>et al.</i> , "Mucoadhesive dosage forms for peptide and protein drug delivery," In: <i>Peptide and Protein Drug Delivery</i> , V.H.L. Lee ed. Marcel Dekker, Inc. New York, pp. 741-767, 1991.
	C19	Liu <i>et al.</i> , "DNA vaccines: A new era in vaccinology," <i>Ann NY Acad Sci</i> , New York, NY, 772: 1995.
	C20	Lofstrom <i>et al.</i> , "Effect of cyclodextrins and polymers on triclosan availability and substantivity in toothpastes in vivo," <i>J Pharm Sci</i> , 88:1254-1258, 1999.

2557817.1

EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)

Atty. Docket No.
NANO:002USD1Serial No.
10/072,320

List of Patents and Publications for Applicant's

Applicant

Russell Mumper and Michael Jay

INFORMATION DISCLOSURE STATEMENT

Filing Date:

February 7, 2002

Group:

1615

(Use several sheets if necessary)

U.S. Patent Documents

See Page 1

Foreign Patent Documents

See Page 1

Other Art

See Page 1

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C21	Mandel, "Antimicrobial mouthrinses: overview and update," <i>J Am Dent Assoc</i> , 125:28-10S, 1994.
	C22	March and Nakamura, "Evaluation of the duration of effect of a bioadhesive vaginal moisturizing gel on vaginal pH," 7 th International Congress on the Menopause, Replens Symposium, Stockholm, Sweden, June 20-22, 1993.
	C23	Markwardt, "Development of hirudin as an antithrombotic agent," <i>Sem Thromb Hemost</i> , 15:269-282, 1989.
	C24	Markwardt, "Past, present and future of hirudin," <i>Haemostasis</i> , 21:11-26, 1991b.
	C25	Markwart, "Hirudin and derivatives as anticoagulant agents," <i>Thromb Haemost</i> , 66:141-152, 1991a.
	C26	Martin <i>et al.</i> , <i>Martin's Physical Pharmacy: Physical chemical principles in the pharmaceutical sciences</i> , Lea & Febiger, Third Ed., Philadelphia, 1983.
	C27	McGhee and Kiyono, "Mucosal immunity to vaccines: Current concepts for vaccine development and immune response analysis," In: <i>J.E. Chadi (ed.) Genetically engineered vaccines</i> , Plenum Press, New York, NY, pp. 3-12, 1992a.
	C28	Park and Robinson, "Physico-chemical properties of water insoluble polymers important to mucin/epithelial adhesion," <i>J Cont Rel</i> , 2:47-57, 1985.
	C29	Rathbone <i>et al.</i> , In: <i>Oral J Mucosal Drug Delivery</i> , M.J. Rathbone Ed., Marcel Dekker Inc., New York, 1996.
	C30	<i>Remington's Pharmaceutical Sciences</i> , 18 th Ed., A.R. Gennard, ed. Mack Publishing Company, Easton, PA, 1990.
	C31	Riehl-Bellon <i>et al.</i> , "Purification and biochemical characterization of recombinant hirudin produced by <i>Saccharomyces cerevisiae</i> ," <i>Biochemistry</i> , 28:2941-2949, 1989.
	C32	Robinson and Torres, "C.A.T. DNA Vaccines," <i>Sem Immun</i> , 9:271-283, 1997.
	C33	Saijo <i>et al.</i> , "Inhibition by amoxanox (AA-673) of the immunologically, leukotriene D4- or platelet-activating factor-stimulated bronchoconstriction in guinea pigs and rats," <i>Int Arch Allergy Appl Immunol</i> , 77:315-321, 1985.
	C34	Saijo <i>et al.</i> , "The antiallergic agent amoxanox suppresses SRS-A generation by inhibiting lipoxygenase," <i>Int Arch Allergy Appl Immunol</i> , 79:231-237, 1986.

25577617.1

EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)

List of Patents and Publications of Applicant's

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Atty. Docket No.
NANO:002USD1Serial No.
10/072,320Applicant
Russell Mumper and Michael JayFiling Date:
February 7, 2002Group:
1615U.S. Patent Documents
See Page 1Foreign Patent Documents
See Page 1Other Art
See Page 1

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C35	Schwagmeier <i>et al.</i> , "Midazolam pharmacokinetics following intravenous and buccal administration," <i>Br J Clin Pharmacol</i> , 46:203-206, 1998.
	C36	Spannagl <i>et al.</i> , "A fast photometric assay for the determination of hirudin," <i>Haemostasis</i> , 21:36-40, 1991.
	C37	Stevens-Simon <i>et al.</i> , "Racial variation oin vaginal pH among healthy sexually active adolescents," <i>Sex Trasm Dis</i> , 21:168-172, 1994.
	C38	Tang <i>et al.</i> , "Genetic immunization is a simple method for eliciting an immune response," <i>Nature</i> , 356:152-154, 1992.
	C39	Taubes, "Salvation in a snippet of DNA," <i>Science</i> , 278:1711-1714, 1997.
	C40	Ulmer <i>et al.</i> , "Toward the development of DNA vaccines," <i>Curr Opin Immun</i> , 8:531-536, 1996a.
	C41	Urisu <i>et al.</i> , "Inhibitory action amexanox on interleukin-3-induced enhancement of histamine releasability of human leukocytes," <i>Aerug</i> , 39(10):1448-1454, 1990. (ABSTRACT)
	C42	Yankauckas <i>et al.</i> , "Long-term anti-nucleoprotein cellular and humoral immunity is induced by intramuscular injection of plasmid DNA containing NP gene," <i>DNA Cell Biol</i> , 12:771-776, 1993.
	C43	Zuckerbraun <i>et al.</i> , "Triposan: cytotoxicity, mode of action, and induction of apoptosis in human gingival cells in vitro," <i>Eur J Oral Sci</i> , 106:628-636, 1998.
	C44	Co-pending U.S. Application No. 09/748,133 filed on December 27, 2000, (NANO:002US).

25577817.1

EXAMINER:

/Michael Hartley/

DATE CONSIDERED:

09/23/2008

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.